IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC. and VISTAKON PHARMACEUTICALS, LLC,	)	
Plaintiffs,	)	
v.	)	
	)	C.A. No. _____
SOMERSET THERAPEUTICS, LLC,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc., and Vistakon Pharmaceuticals, LLC, by way of Complaint against Somerset Therapeutics, LLC, allege as follows:

THE PARTIES

1. Allergan, Inc. ("Allergan") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2525 Dupont Drive, Irvine, California, 92612. Allergan is a global, research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human health.

2. Vistakon Pharmaceuticals, LLC ("Vistakon") is a Florida limited liability company, having a principal place of business at 7500 Centurion Parkway, Jacksonville, Florida, 32256.

3. On information and belief, Somerset Therapeutics, LLC ("Somerset") is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 475 Bernardsville Rd., Mendham, NJ 07945.

4. On information and belief, Somerset is in the business of developing, marketing and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

NATURE OF THE ACTION

5. This is a civil action for patent infringement under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Somerset's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the pharmaceutical product Lastacaft® before the expiration of Plaintiffs' patent covering Lastacaft®'s use.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Somerset is subject to personal jurisdiction in this District because it is a limited liability company organized and existing under the laws of the State of Delaware.

8. Upon information and belief, Somerset has appointed National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware, 19904, as its registered agent for the receipt of service of process.

9. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

ALLERGAN'S NDA AND ASSERTED PATENT

10. Vistakon filed New Drug Application ("NDA") No. 022134, pursuant to which the FDA granted approval for alcaftadine ophthalmic solution 0.25% for the prevention of itching associated with allergic conjunctivitis. Vistakon has assigned all rights, title, and interest

to NDA No. 022134 to Allergan. Alcaftadine ophthalmic solution 0.25% is sold by Allergan under the trade name Lastacaft®.

11. Vistakon is the assignee of U.S. Patent No. 8,664,215 (the "'215 patent"). A copy of the '215 patent is attached as Exhibit A. The '215 patent discloses and claims methods of treating and preventing clinical symptoms of ocular allergy (including ocular itching) comprising the administration once daily of an ophthalmic solution comprising alcaftadine, its pharmaceutically acceptable salts, or mixtures thereof. Allergan is the exclusive licensee of the '215 patent.

12. Pursuant to 21 U.S.C. §355(b)(1), Allergan has submitted information concerning the '215 patent to the FDA in connection with NDA No. 022134, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '215 patent has been listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Lastacaft®.

SOMERSET'S ANDA AND NOTICE LETTER

13. By letter ("Somerset Notice Letter") dated April 12, 2016, and received by Allergan and Vistakon (hereinafter collectively "Plaintiffs") on April 15, 2016, Somerset gave notice that it had submitted ANDA No. 209126 ("Somerset ANDA") to the FDA under 21 U.S.C. §355(j) seeking approval to manufacture, use, sell, offer for sale, or import alcaftadine ophthalmic solution 0.25% (the "Somerset Generic Product"), prior to the expiration of the '215 patent.

14. The Somerset Notice Letter informed Plaintiffs that the Somerset ANDA contained a "Paragraph IV Certification" alleging that the claims of the '215 patent are invalid, unenforceable, and/or will not be infringed by the Somerset Generic Product.

15. On information and belief, Somerset intends to manufacture, distribute, import, use, sell, or offer to sell the Somerset Generic Product for uses that would infringe the claims of the '215 patent, throughout the United States, including within the State of Delaware.

16. This action is being filed within 45 days of Plaintiffs' receipt of Somerset's Notice Letter.

COUNT I – INFRINGEMENT OF '215 PATENT

17. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-16.

18. Somerset submitted ANDA No. 209126 to the FDA under 21 U.S.C. §355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the Somerset Generic Product prior to the expiration of the '215 patent. By submitting this application, Somerset has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

19. On information and belief, the commercial manufacture, use, or sale of the Somerset Generic Product prior to the expiration of the '215 patent will directly infringe the '215 patent under 35 U.S.C. §271(a), will actively induce infringement of the '215 patent under 35 U.S.C. §271(b), and will constitute contributory infringement of the '215 patent under 35 U.S.C. §271(c). Somerset will infringe or aid another in the infringement of at least one or more of the following claims of the '215 patent: claims 1-11.

20. On information and belief, the Somerset Generic Product will have instructions for use that substantially copy the instructions for Lastacaft®. Upon information

and belief, the proposed labeling for the Somerset Generic Product directs the use of the Somerset Generic Product for the following indication: prevention of itching associated with allergic conjunctivitis.

21. Upon information and belief, Somerset has acted with full knowledge of the '215 patent and its claims and without a reasonable basis for believing that it would not be liable for infringement, induced infringement, and contributory infringement of the '215 patent. Notwithstanding this knowledge, Somerset has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Somerset Generic Product with its proposed labeling immediately and imminently upon approval of the Somerset ANDA. Upon information and belief, through such activities, Somerset specifically intends infringement of the '215 patent.

22. Upon information and belief, if the FDA approves the Somerset ANDA, Somerset intends to, and will, infringe, actively induce infringement of, and contribute to the infringement of the '215 patent, and plans and intends to, and will, do so immediately and imminently upon approval.

23. Upon information and belief, Somerset knows that the Somerset Generic Product is especially made or adapted for use in infringing the '215 patent, and that the Somerset Generic Product is not suitable for substantial non-infringing use. Upon information and belief, Somerset plans and intends to, and will, contribute to infringement of the '215 patent immediately and imminently upon approval of the Somerset ANDA.

24. Plaintiffs will be substantially and irreparably harmed if Somerset's infringement of the '215 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

25. Plaintiffs are entitled to the relief provided by 35 U.S.C. §271(e)(4), including an order of this Court that the effective date of the approval of Somerset's ANDA be a date that is not earlier the expiration date of the '215 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

26. On information and belief, Somerset lacked a good faith basis for alleging invalidity of the '215 patent when it filed ANDA No. 209126 and made the Paragraph IV certification. Accordingly, Somerset's Paragraph IV certification was wholly unjustified.

27. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. §§271(e)(4) and 285.

PRAYER FOR RELIEF

28. Plaintiffs request that:

a. Judgment be entered that the '215 patent is valid and enforceable;

b. Judgment be entered that Somerset has infringed the '215 patent under 35 U.S.C. §271(e)(2)(A) by submitting ANDA No. 209126;

c. Judgment be entered that the commercial manufacture, use, offer for sale, and/or sale of Somerset's Generic Product in the United States, and/or the importation of the Somerset Generic Product into the United States, will infringe the '215 patent under 35 U.S.C. §§271(a), (b), and/or (c);

d. A permanent injunction be issued, pursuant to 35 U.S.C. §271(e)(4)(B), restraining and enjoining Somerset, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United

States, of the Somerset Generic Product prior to the expiration date of the '215 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled;

e. If Somerset commercially makes, uses, sells, or offers to sell the Somerset Generic Product within the United States, or imports the Somerset Generic Product into the United States, prior to the expiration of the '215 patent, including any extensions, that Plaintiffs be awarded monetary damages, including treble damages, for those infringing acts to the fullest extent allowed by law, and be awarded prejudgment interest based on those monetary damages;

f. An order be issued pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of any approval of ANDA No. 209126 be a date which is not earlier than the later of the expiration date of the '215 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled;

g. Judgment be entered that this is an exceptional case, and that Plaintiffs are entitled to its reasonable attorney's fees, costs, and expenses pursuant to 35 U.S.C. §§271(e)(4) and 285; and

h. The Court grant such other and further relief as it may deem just and proper under the circumstances.

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